510(k) Summary of Safety and Effectiveness

Date prepared: August 8, 2013

510(k) Owner:
DeRoyal Industries, Inc.
200 DeBusk Lane
Powell, TN 37849
Owner/Operator #1044833

OCT 0 3 2013

510(k) Contact:
Courtney Rinehart
Regulatory Affairs Specialist
865-362-2122
crinehart@deroyal.com

Manufacturer:
Zhejiang Jinhua Huatong Medical Appliance Co., Ltd.
No 23, Meixi Street, Sumeng Cun, Sumeng Xiang,
Wucheng Area, 321051, Jinhua City, Zhejiang Province, China
Owner/Operator #10044444
Registration number pending FDA processing

Trade Name: DeRoyal® Electrosurgical Pencil

Common Name: Electrosurgical Pencil

Classification: Electrosurgical cutting and coagulation device and accessories
21 CFR 878.4400, Class II

Device Product Code: GEI- Electrosurgical, Cutting & Coagulation & Accessories

Substantial Equivalency: DeRoyal Industries Inc.
Electrocautery Pencil- K940909

Indications for Use:
The DeRoyal Electrosurgical Pencil is intended to be used to remove tissue and control bleeding by use of high frequency electrical current. The pencil can be used during electrosurgical procedures for both cutting and coagulation.

Device Description:
Electrosurgery can be used to accomplish any one of three functions in the surgical environment: incise, desiccate, or coagulate.

The "pencil" is the portion of the system that delivers the current to the patient. It is a hand-held device operated by the surgeon or other trained professional. It has switches built into it for hand switching capability.

This is a single use, disposable device. It plugs into the electrosurgical generator via an industry standard three-prong offset plug.

Summary of Technological Characteristics:

Feature	Predicate: K940909	This submission: DeRoyal Electrosurgical Pencil
Button Style	Two buttons for hand switching control	Same as predicate
Rocker Style	One rocking button for hand switching control	Same as predicate

Basis for Substantial Equivalence:
In order to demonstrate substantial equivalence, DeRoyal evaluated the indications for use, materials, and product specifications. Testing has been successfully completed and documented to demonstrate that the proposed device is substantially equivalent to the DeRoyal Electrocautery Pencil.

Test Performed	Conclusion
Biocompatibility	Cytotoxicity, Irritation, Sensitization, System Toxicity, and Haemocompatibility tests were performed and passed according to ISO 10993-1.
Electrical	IEC 60601-2-2:2009 testing was performed and passed when used with over-molded electrodes only.
Sterilization	EO sterilization validation was performed and passed according to ISO 11135:2007. The SAL of the sterilized pencil reached 10^{-6}.
Aging	Aging studies performed according to ASTM F 1980-02. The shelf life was determined to be 3 years.
Package Seal Integrity	Package seal integrity tests were performed and passed according to ISO 11607-1:2006, ASTM F 1929-98, and EN868-5:1999.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

DeRoyal Industries, Incorporated
Ms. Courtney Rinehart
Regulatory Affairs Specialist
200 DeBusk Lane
Powell, Tennessee 37849

October 3, 2013

Re: K132199
Trade/Device Name: DeRoyal® Electrosurgical Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 9, 2013
Received: August 12, 2013

Dear Ms. Rinehart:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K132199

Device Name: DeRoyal® Electrosurgical Pencil

INDICATIONS FOR USE

The **DeRoyal® Electrosurgical Pencil** is intended to be used to remove tissue and control bleeding by use of high frequency electrical current. The pencil can be used during electrosurgical procedures for both cutting and coagulation.

Prescription Use X (Per 21 CFR 801 Subpart D)	OR	Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=13003690056
Date: 2013.10.03 06:53:15 -04'00'

For MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132199

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